DEC 2 0 2011

510(k) Summary – i-STAT Lactate Test

The summary of the 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1900 and CFR 807.92.

The assigned 510(k) number is: K112430

Summary Prepares on: Friday 19 August 2011

Submitted by:
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Contact:
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Establishment Registration Number: 2245578

Identification of Device:
Device Name: i-STAT Lactate Test
Proprietary/Trade Name: i-STAT® Lactate
Common Name: Lactic Acid, Lactate
Device Classification: 1
Registration Number: 21 CFR §862.1450
Panel: Clinical Chemistry
Product Code: KHP

Performance Standards:
No applicable standards

Identification of the Predicate Device:

i-STAT Lactate Test part of the CG4+ Cartridge (K982071)

Indication for Use Statement

The i-STAT Lactate Test is indicated for (1) the diagnosis and treatment of lactic acidosis in conjunction with measurements of blood acid/base status, (2) monitoring tissue hypoxia and strenuous physical exertion, (3) diagnosis of hyperlactatemia.

The i-STAT Lactate Test, as part of the i-STAT System, is intended for the in vitro measurement of lactate in arterial, venous, or capillary whole blood.

Current and proposed labeling for i-STAT Lactate Test

This 510(k) submission supports an additional statement to the "Clinical Significance" section of the labeling.

Current "Clinical Significance" section of the labeling

Elevated levels of lactate are mainly found in conditions of hypoxia such as shock, hypovolemia, and left ventricular failure; in conditions associated with diseases such as diabetes mellitus, neoplasia, and liver disease; and in conditions associated with drugs or toxins such as ethanol, methanol, or salicylates.

Proposed "Clinical Significance" section of the labeling

Elevated levels of lactate are mainly found in conditions of hypoxia such as shock, hypovolemia, and left ventricular failure; in conditions associated with diseases such as diabetes mellitus, neoplasia, and liver disease; and in conditions associated with drugs or toxins such as ethanol, methanol, or salicylates.

Hyperlactatemia is an indicator commonly used to detect tissue hypoperfusion, particularly in the case of sepsis, but also in trauma and surgical settings.

Justification of the Labeling Change

The clinical value of an elevated blood lactate level in patients with sepsis as well as patients with hypoperfusion as the result of trauma or following cardiac surgery has been well established. A comprehensive review of the literature supporting the change to the "Clinical Significance" section has been provided.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

DEC 20 2011

Abbott Point of Care Inc.
c/o Yuko Hartley
400 College Road East
Princeton, NJ 08540

Re: k112430
Trade name: i-STAT Lactate test
Regulation Number: 21 CFR 862.1450
Regulation Name: Lactic Acid Test System
Regulatory Class: Class I, meets limitations of exemptions per 21 CFR 862.9(c)(9)
Product Code: KHP
Dated: November 18, 2011
Received: November 21, 2011

Dear Ms. Hartley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): k112430

Device Name: i-STAT Lactate Test

Indications for Use:
The Lactate Acid Test is indicated for (1) the diagnosis and treatment of lactic acidosis in conjunction with measurements of blood acid/base status, (2) monitoring tissue hypoxia and strenuous physical exertion, (3) diagnosis of hyperlactatemia.

The Lactate Test, as part of the i-STAT System, is intended for the in vitro measurement of lactate in arterial, venous, or capillary whole blood.

Prescription Use __√__ AND/OR Over-The-Counter-Use _____

(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(Please do not write below this line—continue on another page if needed.)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) 112430